



Company Announcement

Nykode Therapeutics Announces Clinical Collaboration with MSD to Evaluate VB10.16 in Combination With KEYTRUDA® (pembrolizumab) in Patients with HPV16-Positive Head and Neck Cancer

Oslo, Norway, December 6, 2022 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced that it has entered into a clinical collaboration and supply agreement with MSD (Merck & Co., Inc., Rahway, NJ, USA), to evaluate Nykode's wholly-owned lead candidate, VB10.16, in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a Phase 1/2a trial in patients with HPV16-positive head and neck cancer.

VB10.16 is an off-the-shelf therapeutic cancer vaccine specifically designed to treat HPV16-induced malignancies. The candidate has reported interim data from a Phase 2 trial in heavily pre-treated cervical cancer patients (NCT04405349). The analysis demonstrated a favorable safety profile, with responses observed in both PD-L1 positive and negative patients (ORR 27% and 17%, respectively). The vaccine-induced significant HPV16-specific T cell responses were associated with clinical responses.

"We are thrilled to collaborate with MSD, a global leader in immuno-oncology, and to work with their highly experienced and talented scientific team," stated Agnete Fredriksen, Chief Business Officer & Co-founder of Nykode Therapeutics. "We see great potential for Nykode's cancer vaccine in combination with MSD's anti-PD-1 therapy to generate a potent immune response in head and neck cancer and provide a meaningful clinical benefit for patients with late-stage disease."

The open-label, dose-finding Phase 1/2a trial will evaluate the safety, immunogenicity, and anti-tumor activity of VB10.16 in combination with KEYTRUDA in patients with unresectable recurrent or metastatic HPV16-positive head and neck squamous cell carcinoma. The trial is anticipated to begin enrollment in Europe during the first half of 2023.

Under the terms of the agreement, Merck will supply KEYTRUDA. Nykode retains all commercial rights to VB10.16 worldwide.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.



About Nykode Therapeutics

Nykode Therapeutics is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies for the treatment of cancer and infectious diseases. Nykode's modular vaccine technology specifically targets antigens to Antigen Presenting Cells, which are essential for inducing rapid, strong and long-lasting antigen specific immune responses and eliciting efficacious clinical responses.

Nykode's lead product candidates are VB10.16, a therapeutic vaccine for the treatment of human papilloma virus (HPV)-16 induced malignancies which demonstrated positive interim efficacy and safety results from its Phase 2 trial for the treatment of cervical cancer; and VB10.NEO, an individualized cancer neoantigen vaccine, which is exclusively out-licensed to Genentech, a member of the Roche Group. Additionally, Nykode is conducting a Phase 1/2 trial with next-generation COVID-19 vaccine candidates.

The Company's partnerships include Genentech within oncology, a multi-target collaboration with Regeneron within oncology and infectious diseases and a collaboration with Adaptive Biotechnologies for COVID-19 T cell vaccine development.

Nykode Therapeutics' shares are traded on the Oslo Stock Exchange (OSE: NYKD). Further information about Nykode Therapeutics may be found at <http://www.nykode.com>.

Forward-looking statements for Nykode Therapeutics

This announcement and any materials distributed in connection with this announcement may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect the company's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of material factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.

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